

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

Sub P. 1

Claim 1 (currently amended): A process for the manufacture of a solid dosage form which is rapidly dissolving in aqueous medium, wherein the solid dosage form comprising an active substance and other pharmaceutical ingredients suitable for a solid dosage and wherein the solid dosage form is a pharmaceutical or veterinary dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of

- (1) either the active substance or part thereof and the other ingredients of the solid dosage form,
or
(2) the other ingredients of the solid dosage form;

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(b) dispensing

- (1) either an auxiliary solvent or
(2) a solution or dispersion of the active substance in an auxiliary solvent
in cavities of a pre-formed container intended for storage of the solid dosage form or molds;

(c) compacting a suitable amount of the powder or granulate prepared according to (a)(1) or (a)(2) above;

(d) putting the compacted powder or granulate prepared according to (c) on the top of the solvent which according to (b)(1) or (b)(2) is in the molds or in the cavities of the pre-formed container intended for storage of the solid dosage form;

(e) removing the auxiliary solvent by applying a drying system to the molds or the cavities of the pre-formed container intended for storage of the solid dosage form after (d); and

(f) removing the dried solid dosage form from the moulds into a suitable storage container or sealing the cavities of the pre-formed container intended for storage of the solid dosage form, respectively.

Claim 2 (previously amended): A process according to claim 1 for the manufacture of a solid, rapidly dissolving pharmaceutical or veterinary dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of
(1) either the intended dose of the active substance or part thereof and the other ingredients of the solid dosage form, or
(2) the other ingredients of the solid dosage form;

(a') transferring the powder or granulate to a combined compacting/dosing system; and

(a'') placing the molds or the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form within the operating range of the combined compacting/dosing system;

(b) dispensing,

(1) either an auxiliary solvent or

(2) a solution or dispersion of the active substance in an auxiliary solvent,
in the molds or in the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form;

(c) compacting - within the combined compacting/dosing system - a suitable amount of the powder or granulate prepared according to (a)(1) or (a)(2) above;

(d) putting the compacted powder or granulate on the top of the liquid which according to (b)(1) or (b)(2) is in the molds or in the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form;

(e) removing the auxiliary solvent by applying a drying system comprising one or more techniques selected from the group consisting of forced warm gas, microwave radiation and reduced pressure, to the units in the moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form; and

(f) removing the dried units from the moulds into a suitable storage container or sealing the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form, respectively.

Claim 3 (previously amended): A process according to claim 1 for the manufacture of a solid, rapidly dissolving pharmaceutical dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of the active substance and all other ingredients of the solid dosage form;

(a') transferring the powder or granulate to a combined compacting/dosing system;

(a'') placing a pre-formed container intended for storage of the solid pharmaceutical dosage form within the operating range of the combined compacting/dosing system;

(b) dispensing an auxiliary solvent in the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form;

(c) compacting - within the combined compacting/dosing system - an amount of the powder or granulate prepared according to (a) above, which amount of powder or granulate contains the intended dose of the active substance;

(d) putting the compacted powder or granulate on the top of the liquid which according to (b) is in the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form;

(e) removing the auxiliary solvent by applying a drying system comprising at least two different techniques selected from the group consisting of forced warm gas, microwave radiation and reduced pressure; and

(f) sealing the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form.

Claim 4 (previously amended): A process according to claim 1, where in step (b) the auxiliary solvent is selected from the group consisting of water, ethanol, acetone, isopropanol and any mixtures thereof.

Claim 5 (previously amended): A process according to claim 1, where in step (c) the density of the compacted powder or granulate prepared is between 300 and 1000 mg/ml.

Claim 6 (previously amended): A process according to claim 1, where in step (c) the density of the compacted powder or granulate is between 400 and 900 mg/ml.

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Claim 7 (previously amended): A process according to claim 1, where in step (c) the amount of powder or granulate which is subjected to compaction contains the intended dose of the active substance.

Claim 8 (previously amended): A process according to claim 1, where in step (e) the auxiliary solvent is removed by applying simultaneously or sequentially at least two different techniques selected from the group consisting of forced warm gas, microwave radiation and reduced pressure.

Claim 9 (previously amended): A process according to claim 1, where in step (e) the auxiliary solvent is removed by applying simultaneously a combination of forced warm gas and microwave radiation.

Claim 10 (previously amended): A process according to claim 1, wherein a solid pharmaceutical or veterinary dosage form for oral administration is manufactured.

Claim 11 (original): A process according to claim 10, wherein a solid pharmaceutical dosage form for oral administration which is in the form of a tablet is manufactured.

Claim 12 (currently amended): A solid dosage form which is rapidly dissolving in aqueous medium, which dosage form comprises

- (1) an active substance,
(2) a filler, and
(3) a disintegration agent selected from the group consisting of croscarmellose Na; agents based on sodium carboxymethyl cellulose, poly-N-vinyl-2-pyrrolidones, polymethylmethacrylates, polysaccharides or synthetic resins.

which dosage form disintegrates when taken into the mouth within 30 seconds, and which dosage form has a density of 300-1000 mg/ml.

Claim 13 (currently amended): A solid dosage form according to claim 12, comprising

- (1) a pharmaceutically or veterinary active substance[.]] and
(2) a filler selected from the group consisting of mannitol, lactose, calcium phosphates, dibasic calcium phosphates, microcrystalline cellulose, cyclodextrine, starch, laevulose, maltitol, polydextrose, sucrose, glucose, inulin, sorbitol or xylitol[[, and]] .
~~(3) a disintegration agent selected from the group consisting of croscarmellose Na; agents based on sodium carboxymethyl cellulose and starch, sodium glycolates of starches, poly-N-vinyl-2-pyrrolidones, starches, polymethylmethacrylates, polysaccharides or synthetic resins.~~

Claim 14 (currently amended): A solid dosage form according to claim 12, comprising
(1) a pharmaceutically or veterinary active substance, and
(2) mannitol, lactose, starch and microcrystalline cellulose[, and]]
~~(3) a disintegration agent selected from the group consisting of croscarmellose Na, agents based on sodium carboxymethyl cellulose and starch, and poly-N-vinyl-2-pyrrolidones.~~

Claim 15 (previously amended): A solid dosage form according to claim 12, consisting essentially of a homogeneous mixture of
(1) at least one pharmaceutically or veterinary active substance,
(2) at least one filler,
(3) at least one disintegration agent, and
(4) optionally pharmaceutically or veterinarily acceptable excipients,
which dosage form disintegrates when taken into the mouth within 30 seconds, and
which dosage form has a density of 400-900 mg/ml.

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Claim 16 (currently amended): A solid dosage form according to claim 15, consisting essentially of a homogeneous mixture of
(1) at least one pharmaceutically active substance,
(2) at least one filler selected from the group consisting of mannitol, lactose, calcium phosphates, dibasic calcium phosphates, microcrystalline cellulose, cyclodextrine, starch, laevulose, maltitol, polydextrose, sucrose, glucose, inulin, sorbitol or xylitol,
(3) a disintegration agent ~~selected from the group consisting of croscarmellose Na; agents based on sodium carboxymethyl cellulose and starch, sodium glycolates of starches, poly-N-vinyl-2-pyrrolidones, starches, polymethylmethacrylates, polysaccharides or synthetic resins,~~
and
(4) optionally pharmaceutically acceptable excipients.

Claim 17 (currently amended): A solid dosage form according to claim 15, consisting essentially of a homogeneous mixture of
(1) a pharmaceutically or veterinary active substance,
(2) mannitol,
(3) a disintegration agent ~~selected from the group consisting of croscarmellose Na, agents based on sodium carboxymethyl cellulose and starch, and poly-N-vinyl-2-pyrrolidones;~~ and
(4) optionally pharmaceutically excipients.

Claim 18 (previously amended): A solid dosage form according to claim 12, wherein the active substance is selected from the group consisting of (a) diclofenac, ketoprofen, ibuprofen, aspirin,

paracetamol, melatonin and pharmaceutically acceptable salts thereof, and (b) pharmaceutically acceptable salts of calcium, magnesium and zinc.

Claim 19 (previously amended): A solid dosage form according to claim 15, wherein the composition contains as one of the excipients (4) a lubricant.

Claim 20 (original): A solid pharmaceutical or veterinary dosage form for oral administration according to claim 19, wherein the lubricant is talc.

Claim 21 (previously amended): A solid dosage form according to claim 15, wherein the composition contains as the excipients (4) comprising a lubricant, and one or more sweeteners.

Claim 22 (previously amended): A solid dosage form according to claim 12, wherein the filler (2) is present in an amount of at least 30 weight-%, and the disintegrating agent (3) is present in an amount of from 0.5 up to 15 weight-% of the total dosage form.

Claim 23 (previously amended): A solid dosage form according to claim 15, which dosage form is manufactured without applying any compression force to the mixture of the components (1), (2), (3) and optionally (4) during the last step of manufacture concerning the solid dosage form.

Claim 24 (previously amended): A solid dosage form according to claim 12, which dosage form is manufactured without applying any freeze-drying process.

Claim 25 (previously amended): A solid dosage form according to claim 15, which dosage form is manufactured by starting with the preparation of a homogeneous mixture of all the components (1), (2), (3) and optionally (4) of the dosage form.

Claim 26 (previously amended): A solid dosage form according to claim 12, which is intended for the pharmaceutical field.

Claim 27 (previously presented): A process for the manufacture of a solid dosage pharmaceutical composition which rapidly dissolves in an aqueous medium, comprising the steps of

(a) preparing solid powder or granule forms of ingredients for the solid dosage composition, the ingredients including an active substance;

(b) compacting a suitable amount of the ingredients including none, some or all of the active substance;

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(c) dispensing in a mold or a cavity of a pre-formed container intended for storage of the solid dosage composition either an auxiliary solvent or an active substance-containing auxiliary solvent if the compacting step (b) does not include all of the active substance, wherein the active substance-containing auxiliary solvent is a solution or suspension of the active substance in the auxiliary solvent;

(d) placing the compacted solid ingredients in the mold or cavity; and

(e) removing the auxiliary solvent from the mold or cavity to form the solid dosage composition after the compacted solid ingredients and the auxiliary solvent with or without the active substance are placed therein.
